REMARKS

Claims 1-20 and 22-31 remain pending in this application and claims 30 and 31 are added. Claims 1-31 are rejected. Claims 1, 11-13 and 22 are amended herein to address matters of form unrelated to substantive patentability issues.

CLAIM REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH, DESCRIPTION REQUIREMENT

Claims 1 and 15 are rejected under 35 U.S.C. § 112, first paragraph, for containing subject matter lacking an adequate written description in the specification. Applicant herein respectfully traverses this rejection. The Office Action states that the limitation "for a time period sufficient" in claims 1 and 15 lacks sufficient description because the specification does not teach "any time period regarding the starting temperature of the sterilization."

The description requirement of the first paragraph of 35 U.S.C. § 112 functions to ensure that the inventor had possession of the subject matter later claimed. How the specification satisfies this requirement is immaterial. It is not necessary that the application describe every claim exactly, but only so much that persons of ordinary skill in the art will recognize from the disclosure that the applicant invented the subject matter with the claimed limitations. *In re Wertheim*,

541 F.2d 257, 191 USPQ 90, 96 (CCPA 1976). In other words, the claimed subject matter need not be described in *haec verba* in the specification in order for the specification to satisfy the description requirement. *In re Wright*, 866 F.2d 422, 9 USPQ2d 1649 (Fed. Cir. 1989). Therefore, a determination of fulfillment of the description requirement under § 112, first paragraph, turns on whether those skilled in the art would understand what is claimed when the claim is read in light of the specification. *Orthokinetics Inc. v. Safety Travel Chairs Inc.*, 806 F.2d 1565, 1 USPQ2d 1081 (Fed. Cir. 1986).

Applicant has set forth in the claims that the peroxide aerosol is introduced for a time period sufficient to keep the interior walls at a permissible temperature of the plastics. The specification on page 3 further notes that the process could even be done twice without exceeding the permissible temperature of the plastic because the peroxide aerosol temperature is kept within the claimed range. An example of a permissible temperature, 55° C, is also provided. From this text and the following text of the specification it is clear that applicant has recognized that the temperature of the plastic must be maintained at or below a permissible temperature. Since the temperature range of the aerosol cited, 60° to 90° C, is above the 55° C example, it is readily evident to one skilled in the art that the applicant has recognized that the timing must be limited to avoid heating the walls beyond a permissible temperature. Since plastics and bottle dimensions vary, no

specific time limit need be set forth to satisfy the description requirement because applicant has set forth the criteria for determination of a time period applicable. One skilled in the art would understand that plastic type and mass are determining factors and adjust a process accordingly. Thus, applicant's disclosure of the criteria indicates applicant was most certainly in possession of the claimed invention at the time of filing, especially the discussion of repeating the process.

Therefore, in view of the above, reconsideration of the rejections of claims 1 and 15 are respectfully requested. Should such objection and rejections be maintained, it is requested that the Examiner explain the grounds for the objection and rejections, addressing the above remarks, to comply with satisfying the burden of the PTO in asserting the rejection. "The burden of showing that the claimed invention is *not* described in the application rests on the PTO in the first instance, and it is up to the PTO to give reasons why a description not in *ipsis verbis* is insufficient." *In re Edwards, Rice, and Soulen* , 196 U.S.P.Q. 465, 469 (CCPA 1978) *citing: In re Salem,* 553 F.2d 676, 682, 193 USPQ 513, 518 (CCPA 1977); *In re Wertheim,* 541 F.2d at 265, 191 USPQ at 98.

CLAIM OBJECTIONS

The claims are objected to due to a grammatical error and a dependency error. The claims are amended to address the informalities. Accordingly withdrawal of the objections is respectfully requested.

CLAIM REJECTIONS UNDER 35 U.S.C. §103(a)

Claims 1-12, 14-20, and 22-29 are rejected as obvious over the Vokins reference in view of the Palaniappan, Dronet, and Reinecke references under 35 U.S.C. §103(a). Claim 13 is rejected as obvious under 35 U.S.C. §103(a) over the afore noted references further in view of the Hatanaka reference which is "only combined" to show a short time period. Claim 30-31 are rejected as obvious under 35 U.S.C. §103(a) over the afore noted references further in view of the Zaelke reference which is cited for teaching using air at a temperature not less than 39.4 ° C. The applicant herein respectfully traverses these rejections.

It is well settled that features of prior art references may not be assembled to establish obviousness using the pending claims as a template. Indeed, the court in *In re Fritch*, 23 USPQ 2d 1780, 1783–84 (Fed. Cir. 1992) stated the following:

> "Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent

> some teaching or suggestion supporting the combination. Under section 103, teachings of references can be combined *only* if there is some suggestion or incentive to do so." (quoting *ACS Hosp. Systems, Inc. v. Montefiore Hosp.*, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984)). . . . The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification.

Thus, the prior art reference must suggest some desirable attribute for making the proposed combination and not just provide an alternative.

In making the above rejections, the Examiner turned to six different references to assemble the limitations presented in the claims. Indeed, independent claims 1 and 15 alone required the Examiner to set forth a combination of four references which, from a careful reading of the references, appear to be only linked together by the fact they relate to sterilization. Otherwise, the references merely have features cherry picked by the Examiner as teaching limitations of the present claims. It is respectfully submitted that references of themselves fail to provide the requisite incentive to make the combination proposed by the Examiner and also teach away from the proposed combination.

The primary reference cited by the Examiner is the Vokins reference which is relied upon as a template for assembling the features of the pending. The Vokins reference discloses a sterilization apparatus for beakers but, aside from such sterilization, fails to address any considerations regarding the focus of the

present invention. The reference makes absolutely no mention of sterilizing plastic containers, nor does the reference provide any recognition of the damage that the temperatures utilized in the processes set forth could inflict upon temperature sensitive plastics.

Vokins teaches an apparatus which first preheats containers to improve sterilization. Col. 3, lines 36-43. Once preheated, the containers are advanced to receive a hydrogen peroxide vapor. Before any introduction of hydrogen peroxide into the containers, the hydrogen peroxide is emitted as a fine spray into a vaporization chamber 3 wherein heated air flows to vaporize the fine spray. Col. 4, lines 1-5. The heated air *has a minimum temperature of 108° C required* for vaporization of a 35% hydrogen peroxide solution. Col. 4, lines 37-40. Once the hydrogen peroxide solution is vaporized, it is then introduced into the container beakers. Thus, the reference teaches one to *first* preheat containers, *second*, vaporize hydrogen peroxide at a temperature of at least 108° C, and once vaporized, *only then* to introduce the hydrogen peroxide vapor into the beaker "to sterilize it in known manner."

The vaporized hydrogen peroxide introduced into the beakers is then dried using hot air. The hot air is initially heated to a temperature of 250° C and reaches the beakers at of temperature of 150° C. Again absolutely no mention or suggestion is made of limiting the temperatures to prevent damage.

In contrast to Vokins reference which initially introduces a hydrogen peroxide *vapor* at a temperature of at least 108° C, the presently claimed invention introduces a hydrogen peroxide *aerosol* into the plastic bottles at a temperature in the range of 60-90° C as recited in claims 1 and 15. This range is significantly lower than the 108° C taught a necessary for vaporization by the Vokins reference. The aerosol is permitted to form condensate on the bottle walls. Furthermore, the time of exposure is limited to prevent heating of the plastic above a permissible temperature for the particular plastic. This is consistent with the overall intent of the present claimed invention, avoidance of overheating temperature sensitive plastic.

In still further contrast to the Vokins reference which uses air heated to at least 150° C, the present invention calls for using sterile air in the temperature range of 90° to 120° C to *activate and evaporate* the hydrogen peroxide condensation formed on the surface of the interior of the bottles. Again a significant temperature difference of at least 30° C exists. The hot air in the Vokins reference is not used for activating and evaporation because the hydrogen peroxide is already introduced into the container as a hot vapor, rather than a heated aerosol. Not a single mention is made of any reason to minimize temperatures in the Vokins disclosure so the hydrogen peroxide is initially introduced as *a high temperature vapor* rather than a *low temperature aerosol*. As

such, the Vokins reference provides no incentive to produce hydrogen peroxide condensate which is to be *activated and evaporated* within the bottle container as is provided in the present invention.

With regard to the Vokins reference, the examiner attempts to find similarity between it and the present invention by bending the meaning of the text of the reference. The examiner inaccurately characterizes the Vokins reference as teaching the following in the response to arguments section of the office action:

> [T]he hydrogen peroxide aerosol (fine spray droplets of hydrogen peroxide is equivalent to the definition of aerosol in col. 2, lines 50-53) is heated to a starting temperature by the heated sterile air (col. 4, lines 37-40) such that a condensation film is formed on the inner surfaces of the containers (in col. 4, lines 28-30, the reference shows the presence of hydrogen peroxide droplets on the inner surfaces of the containers. Those droplets are equivalent to the layer of condensation). Then sterile air heated to a higher temperature than the starting temperature of the peroxide aerosol is blown into the containers to evaporate the condensate (col. 4, lines 44).

Office Action mailed November 30, 2004, page 10. However, such is not the teaching one skilled in the art would derive from reading the Vokins reference.

The examiner recites that the aerosol "is heated to a starting temperature ... such that a condensation film is formed." In actuality, the heating referred to in the Vokins reference at this juncture is the *vaporization* of the aerosol in the vaporization chamber 3 outside of the container to be sterilized. This is in contrast to the claimed invention where a *heated aerosol* is introduced into the bottles to form a condensation film which is only subsequently *vaporized*. In other words,

the presently claimed invention effects *activation and evaporation* within the container to be sterilized while the Vokins references teaches that such heating first takes place outside the container in the external vaporization chamber.

With regard to the claimed formation of a condensation film, the sole portion of the Vokins specification the examiner relies upon for disclosing forming of *condensation* is the indication that "droplets are driven off" in the drying stage. Col. 4, lines 28-30. In the context used, those skilled in the art would merely read the "droplets" as being an undesired result remedied by the drying, and not as a teaching for one to purposefully introduce *aerosol* into a bottle to form a *condensate*, much less to form a condensate to be subsequently activated and evaporated as claimed. As such the reference would not lead one to introduce and acrosol into a container to be sterilized to subsequently form a *condensation film* because the Vokins reference teaches introduction of a vapor with an incidental occurrence of the formation of "droplets." Inadvertent formation of *droplets* by a *vapor* does not induce one to purposefully form a *condensation film* from an *aerosol*.

With regard to the Vokins reference silence regarding any consideration of the problems presented by temperature sensitive plastic, the Examiner turns next to the Palaniappan for teaching the use of hydrogen peroxide and heated sterile air to sterilize plastic bottles and theorizes that Palaniappan makes it obvious to modify

Vokins to sterilize plastic bottles. While Palaniappan discusses sterilizing plastic containers, the process disclosed is clearly foreign to use on temperature sensitive plastics. First, containers are sent to a preheating station using hot air in the range of 200° to 300° C which is far hotter than any temperature used in the claimed invention. Col. 5, lines 8-20. For example, present claims 30 and 31 recite that the permissible temperature is 55° C. The containers in Palaniappan are next subjected to "gas phase hydrogen peroxide emitted from gas nozzles 63 and 64 at approximately 190° C." Col. 5, lines 26-35. Furthermore, the nozzles "*continuously* emit" the ultra heated hydrogen peroxide gas. The containers are subsequently exposed again to the super heated air in the temperature range of 200° to 300° C, and the exposures are again repeated. Such a process has no resemblance to the claimed invention which introduces a hydrogen peroxide aerosol in the range of 60° to 90°C for time sufficient to keep the plastic walls at a permissible temperature and then uses heated air in the temperature range of 90° to 120°C to vapor is the condensation formed by the aerosol. Absolutely no mention is made of limiting the temperature of the walls of the containers in the Palaniappan reference.

The Palaniappan reference, if combined with the Vokins, would only draw one away from the presently claimed invention in that it teaches one to avoid the formation of hydrogen peroxide condensation. Specifically, Palaniappan states:

> The tunnel is maintained at a temperature that inhibits condensation of the hydrogen peroxide gas. The condensation temperature for hydrogen peroxide at atmospheric pressure is 60°C. A preferred temperature of the tunnel is 140°C.

Col. 6, lines 39-45. Claim 1 of the present claimed invention specifically requires the formation of condensation in the containers and subsequent vaporization of the condensation in the container. The Palaniappan teaching is to totally avoid condensation on the containers and place the containers in an environment where such condensation is impossible. The Palaniappan teaching reinforces the treatment of the "droplets" in the Vokins reference as an incidental occurrence which is not desired and should be done away with. Thus, one skilled in the art of sterilization equipment would most certainly be led away from the claimed condensation forming limitation of the present invention.

The examiner goes on to note that the Vokins reference teaches "a starting temperature and an activation temperature" higher than those of the claims. This is correct because the Vokins reference fails to even remotely suggest the present invention which limits heating plastics to be sterilized. To an even further extent, the Palaniappan reference teaches temperatures which are completely off the scale of any envisioned by the claimed invention. In view of these serious shortcomings of the Vokins and Palaniappan references the examiner turns to the Dronet and Reinecke for teaching respectively temperatures of 80° C and 120° C and declares

basically that it would be obvious to use any temperatures within the range of those two temperatures under the rubric of "routine variable optimization." It is respectfully submitted that such reasoning is insufficient to support a determination of obviousness because it goes against the teaching of the Palaniappan reference and has no basis in a prior art suggestion to modify the Vokins reference.

References must be taken in their entireties, including those portions which argue against obviousness. *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 230 USPQ 416, 420 (Fed. Cir. 1986). It is respectfully submitted that one skilled in the art of designing sterilization equipment would most certainly be led away from the present invention when considering the entire disclosure of the Palaniappan reference. In making the present rejection, the examiner has apparently chosen to disregard what the Palaniappan reference teaches as a whole because to apply the idea that routine optimization would lead one from the Vokins reference to the claimed invention is completely contrary to the teaching of the Palaniappan reference.

Optimization involves fine tuning parameters to achieve better results and does not entail going in a completely different direction. The Palaniappan reference stresses the great importance of maintaining the temperatures disclosed. The reference states the following:

> Of the *greatest importance* in practicing this present invention are the temperature of the hydrogen peroxide gas, the temperature of

> the air from the heaters, the temperature of the tunnel and the concentration of the hydrogen peroxide.

Col. 7, line 16-20, (Emphasis added). As noted above, the temperatures of the hydrogen peroxide gas and the tunnel are each far outside the realm of the temperatures of the claim invention. The Palaniappan reference views the achievement of proper levels of sterilization as critical to the operation of the claimed invention. The reference goes on to provide four examples and twenty one tables outlining the importance of maintaining the disclosed temperatures of which none are close to the presently claimed temperatures. Cols.8-25.

Thus, it is respectfully submitted that the proposed combination of references is completely contrary to the teachings of the Palaniappan and Vokins references which provide for much higher temperatures than claimed, teach away from lowering the temperatures, and teach away from the formation of condensation of hydrogen peroxide. Consideration must properly be given to teachings of the prior art which would lead one away from the claimed invention as well as those that might suggest the invention. *Mendenhall v. Astec Industries, Inc.*, 13 USPQ2d 1913, 1939 (Tenn 1988), *aff'd*, 13 USPQ2d 1956 (Fed. Cir. 1989). Still further, none of the references suggests the claimed vaporization of the condensation in the containers formed by an acrosol.

In summary, the cited reference cannot render obvious the present invention for several reasons. A first reason is that none of the references, or even a combination of the references, teaches the claimed process of forming a hydrogen peroxide condensation film in a container using a hydrogen peroxide acrosol in the temperature range of 60° to 90°C and the subsequent *activation and evaporation* of the condensation film *within* the container using heated air at a temperature in the range of 90° to 120°C. Basically, no reference teaches the *activation and evaporation* inside the container.

A second reason is that the primary Vokins and Palaniappan references do not suggest the limiting of exposure to maintain the container wall temperature at a permissible temperature. Indeed, the tunnel temperature in the Palaniappan reference is set to 140°C to prevent condensation. This is an environmental temperature in which the containers remain surrounded in and not briefly exposed, thus ensuring the rise of the container surface temperatures to such levels. Present claims 30 and 31 go on to set the permissible temperature at 55°C.

A third reason is that the Vokins and Palaniappan references teach away from the present invention in two ways. Both seek to avoid the formation of condensation and teach temperature ranges well outside those of the present invention. Palaniappan goes on to stress the great importance of maintaining the high temperatures taught by providing numerous examples showing that deviation

to lower temperatures results in greater bacterial residue. Thus, these references as a whole teach away from incorporation of the temperatures picked from the Dronet and Reinecke references.

And finally, the Examiner's reasoning that routine optimization of variables of the primary reference based on the secondary Dronet and Reinecke references would result in the present invention does not apply. This is because the changes proposed are not routine optimization in that the temperatures claimed are nowhere near the temperatures ranges of the primary references so optimization to a temperature within such ranges would not yield the present invention. Furthermore, optimization cannot be applied where the changes effect a functional difference in the invention. As noted, none of the teaches the *activation and evaporation of a condensation film* inside the container, which is a functional difference based on the presently claimed temperature ranges.

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TIME EXTENSION REQUEST

Applicant respectfully requests a one month extension of time for responding to the Office Action. Please charge the fee of $120.00 for the extension of time to Deposit Account No. 10-1250.

In light of the foregoing, the application is now believed to be in proper form for allowance of all claims and notice to that effect is earnestly solicited. Please charge any deficiency or credit any overpayment to Deposit Account No. 10-1250.

Respectfully submitted,
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